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Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals

Sub-Committee of Experts on the Transport of Dangerous Goods
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Geneva, 23 June – 2 July 2014
Item 11 (g) of the provisional agenda
Issues relating to the Globally Harmonized System of Classification and Labelling of Chemicals: corrosivity criteria

Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals
Twenty-seventh session
Geneva, 2 – 4 July 2014
Item 3 (c) of the provisional agenda
Classification criteria and hazard communication: Work of the TDG-GHS working group on corrosivity criteria

Update on the work of the intersessional informal joint working group on corrosivity criteria

Transmitted by the expert of the Netherlands on behalf of the intersessional joint TDG-GHS working group on corrosivity criteria[1]

Introduction

1. During the twenty-sixth session of the Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), the expert from the United Kingdom transmitted the outcome of the Joint Working Group on Corrosivity in informal document INF.27. The Joint Group confirmed the correlation between the GHS sub-categories 1A, 1B and 1C with Packing Groups I, II and III respectively where these are based on human, animal or *in vitro* data. The challenge was in assigning packing groups in the transport sector when the GHS alternative methods, particularly the additivity and non-additivity approaches, were applied. A further challenge lay in identifying additional criteria for when Packing Group I should be assigned for substances and mixtures classified as GHS sub-category 1A and not included in the Dangerous Goods List.

[1] In accordance with the programme of work of the Sub-Committee for 2013–2014 approved by the Committee at its twenty-sixth session (see ST/SG/AC.10/C.3/84, para. 86 and ST/SG/AC.10/40, para. 14).

2. The Sub-Committee agreed to continue working on the development of a proposal on the basis of the outline presented in paragraph 8 of GHS informal document INF.27. It also agreed to request the TDG Sub-Committee to consider mechanisms to address the issue outlined in the first row of the table, i.e. developing a mechanism to assign substances to packing group I for transport purposes on the basis of considerations that could go beyond hazard classification.

3. The expert of the Netherlands offered to lead the development of the proposal, working with other experts in an intersessional informal joint working group.

4. Experts from the United States of America, Australia, United Kingdom, Germany, Belgium, Netherlands, CEFIC, RPMASA and the European Commission met twice in a teleconference (30 January, 27 February) and an extended group of experts received the correspondence regarding the work of the intersessional informal joint working group. The minutes of these teleconferences can be found in informal document INF.3.

5. This working paper presents a brief summary of the working group discussion and a proposed approach to assign packing groups in the transport sector as developed in the intersessional informal joint working group. To enhance the understanding of the background of the following proposal the reader is referred to informal document INF.3. A proposal for a revised Chapter 2.8 based on the approach presented in this working paper will be submitted as an informal document before the forty-fifth session of the Sub-Committee (TDG) and the twenty-seventh session of the Sub-Committee (GHS).

6. Outside the scope of the teleconferences were discussions on revisions of named entries on the Dangerous Goods List (DGL) as any revisions to named entries on the Dangerous Goods List should follow already established procedures. At this stage in the process, there is no intention to change the named entries on the DGL. Also outside the scope of the discussion were issues associated with the implementation of GHS into supply and use legislation in the European Union (such as translation of classifications done under the European Directives 67/548/EEC and 1999/45/EC to classifications under Regulation 1272/2008) as this is a topic for discussions on global classification lists.

Summary of discussion

7. The intersessional informal working group based its discussions on the proposal in paragraph 8 from informal document INF.27 (GHS, 27th session), taking into account the conclusions from the previous discussions.

GHS hazard class	Transport		Additional criteria and considerations	Transport conditions
1A	8A	Other criteria*	PG I based on "other criteria" PG II	Special packing provisions, limited and excepted quantities and downstream transport provisions
1B	8B		PG II	
1C	8C		PG III	
1**	8		PG II	

* *Other criteria: In case the GHS hazard category is Cat.1A, the results of the individual in vivo/in vitro studies, human evidence and/or experience, may warrant the use of Packing Group I for transport. The criteria are not necessarily hazard based.*

** *Where due to limited hazard information on the transported substance/mixture, the GHS criteria do not allow the assignment of the subcategory.*

8 The group agreed on a set of conditions that the solutions should fulfil. These include no change in the level of safety for transport, the transport conditions will not become more severe, there will be no change in the classification and PG assignments of substances listed by name on the Dangerous Goods List due to this change in criteria, the hazard classification criteria for skin corrosive are consistent between GHS and transport sectors, and the solution should not promote the use of tests conducted on animals.

9. The group agreed to base the solution on elements from the existing system instead of developing a new rationalized approach for assigning packing groups. This latter approach would require extensive amount of time and information, and finding a new rationale that encompassed the current rationale for packing group assignment for both named entries and NOS entries would be quite difficult due to the risk-based case-by-case approach used for assigning packing groups to named entries.

10. The classification GHS Skin Corr 1A can be obtained using OECD 404, OECD 435, OECD 431, bridging principles, assimilation/QSAR/Read-across and the additivity approach. However the group acknowledged that sub-classification into 1A based on these methods will not be possible in all cases.

11 It was concluded that in cases where the hazard classification GHS Skin Corr 1A is based on in vivo testing, in vitro testing such as OECD 435 and OECD 431 or the bridging principles, no additional criteria are needed for assignment of packing group I. It was recognized that different testmethods described under OECD 431 differ in their predictivity for classification into GHS Skin Corr 1A.

12. However, when GHS Skin Corr 1A is the result of the application of the additivity method for mixtures, additional criteria are necessary to discriminate between PG I and PGII as the additivity method is conservative compared to classification based on test results. The group agreed that in this case, a proposal from CEFIC to assign packing group to the mixture based on the packing group of the ingredients of the mixture would be a good starting point for further work.

13. A diagram outlining the proposal from CEFIC is included in the Annex to this paper. This approach includes using the specific threshold values (X_1) associated with the proper shipping name on the Dangerous Goods List to calculate whether a mixture is assigned to packing group I, II or III. If no specific threshold is associated with the proper shipping name, then a generic threshold limit (X_2) will be used. A numerical value for this generic threshold limit was not determined by the intersessional working group.

14. This method requires further work before a conclusion can be reached by the Sub-Committee (TDG). In particular further work is needed to determine the numerical value of the generic threshold limit in order to achieve a sufficient safety margin while maintaining the current ratio in packing group assignments.

15. The group acknowledged that cases are possible where GHS criteria do not allow classification in a subcategory. Examples are cases where only a pH-value, results from in vitro tests using OECD 430 or the non-additivity approach, or when very little information is available. However, for transport, it is still necessary to assign a packing group to these materials.

16. The group agreed that in those cases, a default packing group would be assigned. The default packing group could be either PG I or PG II. However there was no consensus in the intersessional joint working group on which packing group would be most appropriate as the default. In either case, provisions for assigning lower or higher packing

groups could be considered based on available information. The group concluded that more work was needed before a decision by the Sub-Committee (TDG) could be made on the most appropriate default packing group assignment, and when the default packing group could be varied.

Questions

17. The Sub-Committees (TDG) and (GHS) are invited to consider the following modification of the proposal for transport to take account of GHS criteria in the classification of substances and mixtures not listed by name:

GHS hazard classification	Transport class	Packing group	Transport conditions
1A based on OECD 404 OECD 435 OECD 431 Bridging principles	8A	PG I	Special packing provisions, limited and excepted quantities and downstream transport provisions
1A based on additivity	8A	[PG I, II or III based on "threshold limits"]	
1B	8B	PG II	
1C	8C	PG III	
1	8	[PG I] [PG II]	

***NOTE**: The table outlines a general approach for a possible solution. Further discussions are needed on how to incorporate this framework, including which terminology is to be used, into a proposal for a text for a new chapter 2.8 in the Model Regulations.*

18. Do Sub-Committees TDG and GHS agree with the general approach presented (i.e. should the work on this approach continue)?

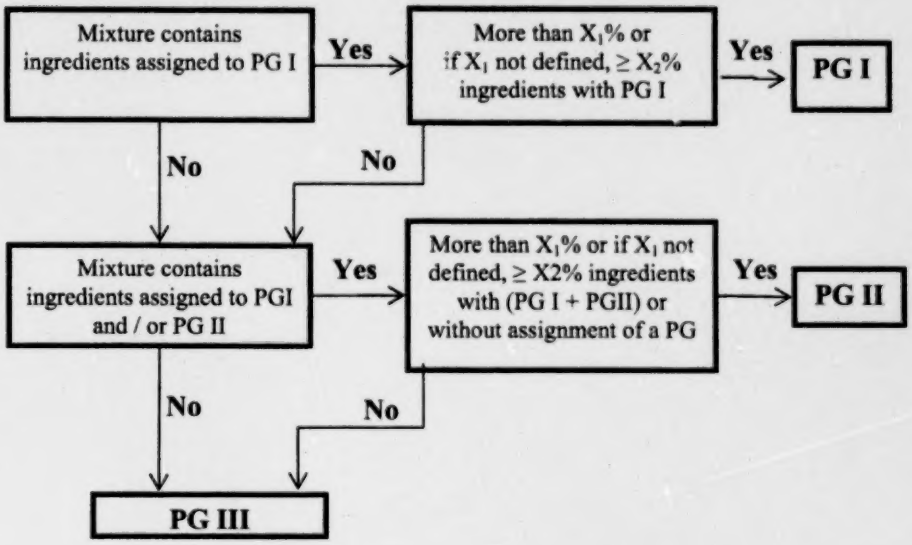
19. Do Sub-Committees TDG and GHS agree that the final two issues to resolve are within the mandate of the UN SCE TDG?

20. Does the Sub-Committee TDG agree to elaborate the diagram included in Annex I?

21. When the available data do not allow GHS sub-classification, is the preference of the Sub-Committee TDG for PG I or PG II?

Annex I

Diagram as presented by CEFIC in the intersessional informal joint working group


Mixture contains ingredients assigned to PG I
Yes
More than X_1% or if X_1 not defined, ≥ X_2% ingredients with PG I
Yes
PG I
No
No
Mixture contains ingredients assigned to PGI and / or PG II
Yes
More than X_1% or if X_1 not defined, ≥ X2% ingredients with (PG I + PGII) or without assignment of a PG
Yes
PG II
No
No
PG III

Explanation of X:

X_1 = specific concentration limits as listed in or determined according the United Nations Model Regulations

X_2 = general concentration limit (e.g. 80 - 50 %), in case no SCL listed in the United Nations Model Regulations